CPMA

COLOR PIGMENTS MANUFACTURERS ASSOCIATION, INC.

January 14, 2004 JAN 1 4 2004

Dr. C. W. Jameson
Report on Carcinogens
National Toxicology Program
79 Alexander Drive
Building 4401, Room 3118
Research Triangle Park, NC 27709

Re: Comments of the Color Pigments Manufacturers Association, Inc. on the Report on Carcinogens Regarding the National Toxicology Program Review Process and Evaluation Criteria Used for Listing Substances

Dear Dr. Jameson:

I am writing on behalf of the Color Pigments Manufacturers Association, Inc. ("CPMA"), with respect to the National Toxicology Program ("NTP") Report on Carcinogens (the "Report") regarding the review process and evaluation criteria used for Listing substances in the Report. These comments are provided in response to the public notice from the NTP indicating that NTP is accepting comment on its review process and evaluation criteria. NTP is accepting public comments both in written submissions and from interested parties in a public hearing now scheduled for January 27 and 28, 2004.

The CPMA is an industry trade association representing small, medium and large color pigment manufacturers throughout Canada, Mexico and the United States, accounting for approximately 95% of the production of color pigments in these countries.

Color pigments are widely used in product compositions of all kinds, including paints, inks, plastics, glass, synthetic fibers, ceramics, colored cement products, textiles, cosmetics, and artists' colors. Color pigment manufacturers located in other countries with sales in Canada, Mexico and the United States and suppliers of intermediates to the pigments industry are also members of the association.

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The CPMA has commented frequently to the NTP on various specific listing evaluations for substances proposed for listing in the Report. Many of these comments have been focused on the classification of metal compounds in the Report. In general, we believe that the NTP too often chooses a one size fits all toxicological evaluation for metals and metal compounds even though the science does not support such an approach. Metal compounds vary widely by bioavailability, toxicity and potential exposure. The assumption implicit in many of the articles involving metals within the Report is that all compounds of a metal, which can number in the thousands, share the same toxicological properties of specific, invariably soluble or easily absorbed, compounds which are used in animal experiments. Our involvement with the NTP has included our recent comments on the Report's current listing of lead chromate in a class of compounds "known to be human carcinogens".

Specific Comments

In our opinion any decision to classify a substance as a known human carcinogen should only be taken on the basis of incontrovertible epidemiological evidence which clearly demonstrates that the substance in question is the causal agent and not in association with other, possibly related substances, which may be the causal agents.

Furthermore, reliance on animal studies under artificial exposure conditions or upon in-vitro studies should not provide sufficient grounds to determine that a substance is a known human carcinogen. At most, such studies might in some cases justify the classification, "reasonably anticipated to be a human carcinogen". Even this classification should be based upon good evidence from epidemiological studies of human exposures.

Wherever possible, listing classes of chemical substances should be avoided. Hexavalent chromium provides a good example. There are relatively few substances that have been proven to be human carcinogens. This is because proof can only be obtained through epidemiological studies under normal circumstances. Most known human carcinogens that have significant commercial use, would readily lend themselves to a targeted individual listing in the Report rather than the broader group classification approach being proposed. For example, the number of hexavalent chromium compounds that have been shown to be human carcinogens may be less than ten, and is exclusively populated by compounds which yield significant soluble chromium under environmental and physiological conditions. See CPMA petition and follow up correspondence dated January 6, 2004. A recent report by the Science Advisory Board ("SAB") of the EPA underscores these concerns. In its assessment of EPA's attempts to describe inorganic metal compounds a persistent bioaccumulative and toxic in an analysis procedure derived from assessing certain limited insoluble lipophilic organic compounds, the SAB determined that separate criteria must be used to assess these characteristics for metals. Additionally, metal compounds should be addressed individually since bioavailability and toxicity may vary widely in individual compounds containing the same metal ion. (cite Science Advisory Board reviews of EPA's Framework for Assessing metals.)

We hope these comments will assist the NTP in improving the current system of evaluating compounds for inclusion in the Report. Please call me at the above number if there are any questions or comments.

Thank you for consideration of these issues.

Sincerely,

[Redacted]

J. Lawrence Robinson
President

Attachments